



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2021-0066; FRL-8671-01-OCSP]

#### Emamectin benzoate; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of emamectin benzoate in or on soybean, seed. Syngenta Crop Protection, LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0066, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information

on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION**

### **I. General Information**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

#### *C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-

HQ-OPP-2021-0066 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0387, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of March 22, 2021 (86 FR 15162) (FRL-10021-44), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8817) by Syngenta Crop Protection, LLC, 410 Swing Road, Greensboro, NC 27409. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of insecticide emamectin benzoate (a mixture of a minimum of 90% 4'-

epi-methylamino-4'-deoxyavermectin B1a and a maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B1b benzoate), and its metabolites 8,9 isomer of the B1a and B1b component of the parent insecticide in or on soybean, seed at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <https://www.regulations.gov/docket/EPA-HQ-OPP-2021-0066>. There were no comments received in response to the notice of filing.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for emamectin including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with emamectin follows.

In an effort to streamline *Federal Register* publications, EPA is not reprinting sections of the rule that would repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains

unchanged, the content of those sections would not vary between tolerance rulemakings, and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for emamectin, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to emamectin and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

*Toxicological profile.* The Toxicological Profile of emamectin remains unchanged from the Toxicological Profile in Unit III.A. of the August 27, 2019 rulemaking (84 FR 44718) (FRL-9997-10). Refer to that section for a discussion of the Toxicological Profile of emamectin.

*Toxicological points of departure/Levels of concern.* The Toxicological Points of Departure/Levels of Concern used for the safety assessment remain unchanged from Unit III.B. of the August 27, 2019 rulemaking. For a summary, refer to that discussion.

*Exposure assessment.* Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerance. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III. C. of the August 27, 2019 rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new use of emamectin on soybean, seed. All other assumptions in the exposure assessments for emamectin remain the same as in the August 27, 2019 rulemaking.

*Drinking water and non-occupational exposures.* Drinking water exposures and residential (non-occupational) exposures are not impacted by the new use, and thus have not changed since the last assessment.

There are no proposed residential uses of emamectin that would result in residential

exposures. As a result, there are no residential risk estimates recommended for use in the aggregate risk assessment for emamectin.

*Cumulative exposures.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” For the new uses of emamectin, the quantitative exposures to residues of emamectin remain unchanged, and the cumulative exposures remain identical to those as assessed within the 2021 cumulative assessment. There are no risks of concern resulting from these cumulative exposures.

*Safety factor for infants and children.* The scientific information underpinning EPA’s prior safety factor determination remains unchanged from the August 27, 2019 rulemaking. EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the August 27, 2019 rulemaking for a discussion of the Agency’s rationale for that determination.

*Aggregate risks and determination of safety.* EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency’s level of concern: 30% of the acute population adjusted dose (aPAD) for children 1 to 2 years old, the population group of concern. Chronic dietary risks are below the Agency’s level of concern: 3.8% of the chronic population adjusted dose (cPAD) for children 1 to 2 years old, the group with the highest exposure. Emamectin is classified as “Not likely to be Carcinogenic to Humans”, therefore, a cancer dietary exposure

analysis was not performed.

There are no registered uses of emamectin that would result in residential exposure; therefore, aggregate exposure and risk estimates are equivalent to the dietary exposure and risk estimates and are not of concern. Using the exposure assumptions described for acute and chronic exposures, EPA has concluded the combined dermal and inhalation exposures result in aggregate margins of exposures for handler scenarios ranging from 200 to 27,000 and post-application scenarios ranging from 48,000 to 750,000 , which are not of concern because they exceed EPA's level of concern (MOEs less than or equal to 100).

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to emamectin residues. More detailed information about the Agency's analysis can be found at <http://www.regulations.gov> in the document titled "Emamectin Benzoate; Human Health Risk Assessment for a Proposed New Use on Soybean" in docket ID number EPA-HQ-OPP-2021-0066.

#### **IV. Other Considerations**

##### *A. Analytical enforcement methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the August 27, 2019 rulemaking.

##### *B. International residue limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has not established MRLs for residues of emamectin on soybeans.

#### **V. Conclusion**

Therefore, tolerances are established for residues of emamectin benzoate (a mixture of a minimum of 90% 4'-epi-methylamino-4'- deoxyavermectin B1a and a maximum of 10% 4'-epi-methylamino-4'deoxyavermectin B1b benzoate) and its metabolites in or on in or on the soybean, seed at 0.01 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government



and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 29, 2021.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.505, add alphabetically the entry “Soybean, seed” to table 1 to paragraph (a)(1) to read as follows:

**§ 180.505 Emamectin; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * *	* * *
Soybean, seed	0.01
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